

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUL 14 1995

Mr. Jeffrey I. Stein
Regulatory Affairs Manager
Ciba Seeds
Agricultural Biotechnology
Ciba-Geigy Corporation
3054 Cornwallis Road
Research Triangle Park, North Carolina 27709-2257

Dear Mr. Stein:

This is in regards to the premarket notification on genetically modified corn, Event 176 Corn submitted by Ciba-Geigy on March 2, 1995. According to Ciba-Geigy, Event 176 Corn has been modified to express a δ -endotoxin gene from *Bacillus thuringiensis*.

This submission informed FDA of the steps taken by Ciba-Geigy to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted it is our understanding that Ciba-Geigy has concluded that corn grain (kernels) derived from the new variety is substantially equivalent in composition, safety, and other relevant parameters from corn grain currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0024. This file will be maintained in the Office of Premarket Approval.

Based on the information you have presented we have no additional questions concerning grain from Event 176 corn at this time. However, as you are aware, it is Ciba-Geigy's continued responsibility to ensure that foods, including silage, the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247 HFS-13 BNF0024
HFV-221(Price)